

### REMARKS

Claims 8-10 have been added by the present amendment and therefore claims 4 and 6-10 are pending in the present application. Claim 4 has been amended to correct a typographical error and to recite that the log P value is "not less than 3.00." Support for the latter claim amendment can be found on page 6, lines 1-4 of the specification. Support for newly added claims 8-10 can be found on page 7, lines 3-8 and line 11.

#### Claims 4 and 6-10 Are Not Anticipated or Rendered Obvious by Fukuyama

Claims 4 and 6-7 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by EP 0743067 A2 to Fukuyama ("Fukuyama"). Applicants respectfully traverse this rejection as Fukuyama does not teach a compound with a log P value of "not less than 3.00," as recited in claim 4. Specifically, amended claim 4 recites a "method for adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent to adsorb and remove the enterotoxin" wherein the adsorbent comprises a compound with a log P value of "not less than 3.00 as immobilized on a water-insoluble carrier." Therefore, the compound recited in the method of claim 4 has a log P value of not less than 3.00. Fukuyama does not teach or suggest any compound with a log P value of not less than 3.00. Instead, Fukuyama describes amino compounds including sec-octyl-amine, 6-amino-n-caproic acid, 3-amino-1-propene,  $\alpha$ -amino-isobutyric acid, aminopyridine, aminobenzenesulfonic acid, diethylenetriamine, triethylenetetramine, tetraethylenepentamine, dipropylenetriamine, N-methyldiaminodiethylamine, and polyethyleneimine, all of which have a log P value of less than 3.00. Accordingly, Fukayama does not anticipate claim 4 (and all claims that depend therefrom).

Furthermore, Fukayama does not render obvious claim 4 because of the superior enterotoxin adsorbing results rendered by using a compound with a log P value of not less than 3.00 as compared to using a compound with a log P value of less than 3.00 (See results of Example 1 using n-hexadecylamine, which has a log P value of not less than 3.00, compared to the results of Example 2 using n-octylamine, which has a log P value of less than 3.00).

#### Claims 4 and 6-10 Are Not Anticipated or Rendered Obvious by Nagaki in view of Hirai

Claims 4 and 6-7 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious by the Nagaki *et al.* Journal of Med. Microbiol., Vol. 38, pages 354-359 (1993)

("Nagaki") in view of EP 0993834A1 to Hirai ("Hirai"). Applicants respectfully traverse this rejection as there is no motivation to combine the teachings of Nagaki with the teachings of Hirai and there is no reasonable expectation that such a combination would be successful.

In the last office action, the Examiner stated that it would be expected that the additional of adsorbents, as described by Hirai, to the adsorbents used in the method of removing enterotoxins from body fluids, as described by Nagaki, can be effective in removing enterotoxins from body fluids because Hirai has demonstrated that the adsorbents comprising compounds which have a log P value of at least 2.50 can be used to remove toxic shock syndrome toxin-1 (TSST-1), which is structurally closely related to enterotoxins. However, Nagaki merely describes that enterotoxins and TSST-1 are structurally related. Nagaki does not teach or suggest that TSST-1 and enterotoxins have similar adsorption properties. Structural similarity of different compounds does not necessarily mean that such compounds will have similar adsorption properties. Nagaki carries out experiments for the adsorption of enterotoxin A, but does not carry out experiments for the adsorption of TSST-1. The description that both the toxins are structurally related does not provide motivation to a person skilled in the art to apply the adsorbent for TSST-1 of Hirai to the adsorptive method for enterotoxin A of Nagaki. Furthermore, neither reference provides a sufficient basis for a reasonable expectation of success as there is no expectation that the adsorbent for TSST-1 of Hirai can adsorb enterotoxin A efficiently. For at least these reasons, claim 4 (and all claims that depend therefrom) are not rendered obvious by Hirai in view of Nagaki.

**CONCLUSION**

It is respectfully submitted that the subject application is now in condition for allowance, which action is earnestly solicited.

The Examiner is invited, upon consideration of the foregoing response, to contact Applicant's representative to discuss any issue that would expedite allowance of the subject application.

The Commissioner is authorized to charge any fees required under 37 C.F.R. §1.16 and/or §1.17 in connection with this filing, or to credit any overpayments, to Deposit Account 11-0600.

Respectfully submitted,

KENYON & KENYON

1/5/04

By:   
Zeba Ali  
Reg. No. 51,392

KENYON & KENYON  
1500 K Street, NW - Suite 700  
Washington, DC 20005  
telephone: 202-220-4200  
facsimile: 202-220-4201  
480003